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November 6, 2000

BY FACSIMILE/CONFIRMATION COPY BY MAIL

Dockets Management Branch
U.S. Food and Drug Administration
5630 Fishers Lane
Room 1061 (HFA-305)
Rockville, Maryland 20852

Re: FDA Docket No. 00N-1380; Human Bone Allograft: Manipulation and Homologous Use in Spine and Other Orthopedic Reconstruction and Repair; Extension of Comment Period for August 2 Public Meeting

Dear Sir or Madam:

The purpose of this letter is to express our concern over the manner in which FDA has handled the extension of the comment period for the above-referenced docket. Although an extension was granted, FDA has failed to publicize the extension in the Federal Register or on the FDA website.

The July 18, 2000 Federal Register notice announcing the August 2 public meeting advised that interested parties could submit written comments until September 1, 2000. Well in advance of this deadline, several interested parties, including the undersigned, wrote to request an extension. An extension of the comment period was requested, for among other reasons, to permit interested parties – including those who attended the meeting and those who could not attend the meeting – adequate time to review the transcript once it became available, and submit informed responses to the important issues discussed. The transcript was not made available until August 17.

00N-1380

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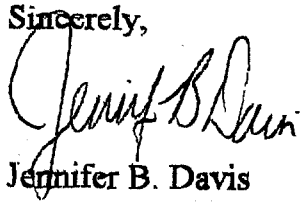
Just prior to the September 1 deadline, FDA informally notified one interested party who requested additional time that the agency would extend the comment period by 60 days, until October 31. FDA did not similarly notify other interested parties who requested extension. More significantly, the agency did not publish a notice of extension in the Federal Register or on its website. Notifying a single party of the extension neither serves the purpose of granting an extension nor complies with the Administrative Procedure Act.

Although we and other parties who requested more time learned of the extension from the informally notified party, FDA's failure to notify the public defeats a primary reason for granting the extension. Typically, when FDA extends a comment period, interested parties other than those who requested the extension take advantage of the renewed opportunity to submit comments. In this case, however, interested parties who would have submitted comments but for the September 1 deadline were never informed that the comment period was extended.

Given the importance of the issues involved, FDA needs to correct this error. Therefore, the agency should immediately issue a Federal Register notice extending the comment period for an additional 45 days from the date of the notice.

Sincerely,



Jennifer B. Davis

JBD/tec